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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,508

Applicant(s)

DORKEN ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-10, 16, 18-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 6-10, 16 and 18-21 is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The specification has been amended; claim 17 has been canceled; claims 1-3, 6-10, and 16 have been amended; and claims 22-30 have been added by the amendment dated October 1, 2004.

Claims 1-3, 6-10, 16, 18-30 are pending for examination.

While the claim amendment in various forms have obviated all rejections and/or objections as set forth in the previous office action, the newly added claims have introduced a new ground of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly added claims 22-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While applicant cancels claim 17, which was rejected due to new matter under 35 USC 112, first paragraph, the newly added claims are written in even a broader scope than that of claim 17. Thus, the claims are rejected under 35 USC 112, first paragraph,

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because the claims introduce new matters into the as-filed application. This ground of rejection has been set forth before in the previous rejection of record and hereby stated in a modified form so as to properly apply to the newly added claims. More specifically, the newly added claim now embrace a method for expressing a transgene in a mammal, which is not necessarily limited to tumor bearing mammal and/or tumor cells *in vivo*. The claims can be reasonably construed as to embrace an *in vivo* gene expression method in a mammal for various usages such as gene therapy methods to correct a disease, wherein the YB-1 promoter is needed for expression of a therapeutic transgene, or even the method as previously claimed in canceled claim 17. As set forth previously, the specification neither provides an explicit or implicit support for the claimed subject matter at the time the invention was made. Thus, this is a new matter rejection. A close review of the as-filed specification demonstrates that:

The invention was thus based on the task of developing a vector with an expression cassette containing a tumour-specific promoter which only expresses a relevant gene chemo-resistant tumour cells. This gene therapy vector is thus to be used in tumour cells which are already chemo-resistant and thus no longer react a conventional chemotherapy. [see page 4].

The specification, particularly pages 4 and 5, as a whole does not contemplate a generic method of either expressing a transgene in a generic mammal such as non-tumor bearing mammals for the purpose of therapy, nor does it contemplate a method of elevating the serum level of a transgene product by administering the claimed vector of claim 1 to a mammal. See claim 24. The specification as a whole only provides written support for a method of enhancing an expression of a transgene product in proliferating tumor cells or chemo-resistant tumor cells. See pages 4 and 5 and

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abstract. Applicant on page 8 of the response appears to suggest that since it is well known in the art that adenoviral vectors are used to express a variety of genes in cells of humans, monkey, rats, mice and pigs, and are used in *in vivo* gene transfer studies, applicant is entitled to claim such methods for patentability, *even though* such was not envisioned by applicants at the time the invention was made. Furthermore, the claimed invention is drawn to the make and combination use of two MCS, the YB-1 promoter in an expression vector, such as an adenoviral vector for usage in targeted expression in proliferating tumor cells or chemo-resistant tumor cells. Such claimed invention is not simply directed to an adenoviral vector for use in gene transfer studies or expression of genes in humans, pigs, monkeys as asserted now by applicant in the latest response. Moreover, a close review of embodiment 2 or Figure 4 only demonstrates an exemplified SCID mouse model, which shows a method of increasing the serum content of a human alpha antitrypsin (hAAT) gene product from proliferating hepatocytes, wherein the method comprises the use of adenoviral vectors that drive hepatocytes into proliferation, wherein the vectors contains an expression cassette having the Yb-1 promoter operably linked to the hAAT transgene. Figure 4 demonstrates the same. The claimed method as set forth in the base claim neither recites the use of an adenoviral vector nor tumor proliferating hepatocytes nor hAAT gene in the body of the claim. Given the fact that the specification as a whole is meant to contemplate a method of using the claimed vector to drive specific expression of a transgene in proliferating tumor cells, see pages 4 and 5, the exemplified *in vivo* SCID mouse model is merely a demonstration of applicant's intended usage of the claimed vector to drive

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specific gene expression in proliferating tumor cells. The model is employed to simply prove the proliferation-specific activity of the YB-1 promoter. While the exemplified SICD mouse model contains a step of measuring the serum level of the hAAT gene product at the third day after the administering step, the exemplified model is not the same as claiming broadly now a method for expressing in a mammal a transgene comprising the gene transfer vector of claim 1. At best, the specification as a whole has a written support for a method of enhancing gene expression in tumor proliferating cells or chemo-resistant tumor cells, said method comprising administering the claimed vector of claim 1 to tumor proliferating cells or chemo-resistant tumor cells.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invent.

Claim 22 recites "A method for expressing in a mammal, a transgene comprising the gene transfer vector of claim 1". However, it is not apparent how a transgene, which is basically a coding segment of genomic or cDNA sequence could comprise the gene transfer vector of claim 1, which itself not only comprises a transgene but also restriction enzyme sites. Clarification is requested. Perhaps applicant is intended to claim "A method for expressing a transgene in a mammal, the method comprising...".

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Regardless, the claim remains rejected under 35 USC 112, first paragraph, as set forth above.

Applicant's response (page 8 of the response dated October 1, 2004) has been considered by the examiner but is not found persuasive for the reasons set forth in the stated rejection.

Claims 1-3, 6-10, 16, 18-21 are in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0804**.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Central Fax number, which is **571-273-8300**.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dave Nguyen
Primary Examiner
Art Unit: 1632



DAVE TRONG NGUYEN
PRIMARY EXAMINER